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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/601,181	06/20/2003	George E. Barringer JR.	3551.1003-000	6784	
21005 7590 05/24/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C.			EXAMINER		
530 VIRGINIA	530 VIRGINIA ROAD			VATHYAM, SUREKHA	
P.O. BOX 9133 CONCORD, MA 01742-9133			ART UNIT	PAPER NUMBER	
,			1753		
			MAIL DATE	DELIVERY MODE	
			05/24/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Summany	10/601,181	BARRINGER, GEORGE E.				
Office Action Summary	Examiner	Art Unit				
	Surekha Vathyam	1753				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was realiure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	l. ely filed the mailing date of this communication. C (35 U.S.C. § 133).				
Status		•				
1)⊠ Responsive to communication(s) filed on 16 M	arch 2007.					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
• • • • • • • • • • • • • • • • • • • •	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) 1-5 and 7-45 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-5 and 7-45</u> is/are rejected.						
7) Claim(s) is/are objected to.	· · · ————————————————————————————————					
•	8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers		•				
9) The specification is objected to by the Examine	r.					
10)⊠ The drawing(s) filed on <u>16 March 2007</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal F					
Paper No(s)/Mail Date 6) Other:						

Art Unit: 1753

DETAILED ACTION

Drawings

- 1. The drawings were received on 16 March 2007. These drawings are not acceptable. In response to the drawing objections raised by the examiner in the office action mailed 13 October 2006, the applicant has provided replacement drawing sheets which address some of the objections especially with regards to figs. 7A and 9. However, the replacement drawings for a number of figures have numerous differences from the originally presented drawings filed on 1 March 2004, in terms of content, accuracy and reference character use. A few examples are: replacement drawing Fig. 2 is missing reference characters 202 and 200 and +- signs in many parts of the figure when compared with fig. 2 originally presented; replacement drawings Figs. 4, 6, 7A, 7B, 7D, 8 10, 12 17 each have errors in depiction of figures or have reference characters either missing or duplicated or transcribed incorrectly or have "new matter" added. The examiner recommends that the applicant submit the originally presented drawings for all figures except for those where corrections are made to overcome objections.
- 2. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37

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Application/Control Number: 10/601,181

Art Unit: 1753

CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Page 3

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "100" has been used to designate both a macromolecule preparation process (page 1, lines 11 – 12) and apparatus (page 6, line 15). The amendment to the specification page 6, line 15 filed on 16 March 2007 does not clarify the use of "100" for both a process and apparatus. It appears page 6, line 15, should be amended to read - -a process for - - instead of "an apparatus for" to be consistent with page 1, lines 11 – 12. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Application/Control Number: 10/601,181

Art Unit: 1753

5. Claims 1 – 5 and 7 – 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 18, 19, 20, 21, 24, 38, 39, 40, 41, 44 and 45 each have been amended to include the limitation "a waste chamber". The specification as originally filed makes reference to a waste site or waste but not to a waste chamber. Hence this limitation is not supported by the specification. In addition, some of the dependent claims that further limit the parent claim with respect to the chambers contained therein do not find support in the specification as originally filed when applied to the waste "chamber". For example claim 8 recites the limitation, "an output valve at each chamber" and the waste "chamber" does not have an output valve described in the specification. Similarly in claim 10, "a fluid level sensor at each chamber" is recited and in claim 31 "sensing the fluid level in at least one chamber" is recited. However a fluid level sensor in a waste "chamber" does not find support in the specification. Also, claim 29 recites the limitation, "directing liquid from each chamber to a waste site, there being a valve between each chamber and the waste site", which when applied to the waste "chamber", does not find support in the specification. Numerous claims have similar "new matter" from the addition of the term "chamber" to waste.

Page 4

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1753

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation, "pressurizes one chamber compared to the other chamber" in line 2 of the claim. Parent claim 4 comprises three chambers – inlet chamber, waste chamber and outlet chamber. It is unclear which one of the three chambers is being referred to as "the other chamber" in claim 5.

8. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 includes an outlet chamber and parent claim 24 includes an inlet chamber and a waste chamber. Claim 26, line 3 recites the limitation, "creating a pressure differential between the chambers". It is unclear which two chambers of the three claimed are used in this limitation.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Application/Control Number: 10/601,181

Art Unit: 1753

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-5 and 7-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,169,599 in view of Swerdlow et al. (US 5,935,522). Specifically, instant independent claims 1, 18, 19, 20, 21, 24, 38, 39, 40, 41, 44 and 45 each are unpatentable over each of independent claims 1, 21 and 22. A one-way test for obviousness-type double patenting has been applied, as the application for US patent No. 7,169,599 was filed on the same day as the instant application.

Regarding instant independent claims 1, 18, 19, 20, 21, 24, 38, 39, 40, 41, 44 and 45, independent claims 1, 21 and 22 of US patent No. 7,169,599 each recite all the limitations except for the explicit disclosure of a capillary electrophoresis unit.

Swerdlow ('522) teaches a capillary electrophoresis unit (see fig. 1 and column 8, lines 28 – 45).

It would have been obvious to one of ordinary skill in the art to modify the method of US patent No. 7,169,599 to include the capillary electrophoresis unit taught by Swerdlow ('522) in the biofluid process site because as Swerdlow ('522) explains combining automated fluidic techniques with capillary electrophoresis obviates the disadvantages of manual manipulation by technicians and improves efficiency (column 6, lines 46 - 65).

Art Unit: 1753

11. Claims 1-5 and 7-45 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1, 25 - 27 of

copending Application No. 11/604440 in view of Swerdlow et al. (US 5,935,522).

Specifically, instant independent claims 1, 18, 19, 20, 21, 24, 38, 39, 40, 41, 44 and 45

each are unpatentable over each of independent claims 1 and 25 – 27. A one-way test

for obviousness-type double patenting has been applied, as the application for

Application No. 11/604440 was filed earlier than the instant application.

Regarding instant independent claims 1, 18, 19, 20, 21, 24, 38, 39, 40, 41, 44

and 45, independent claims 1 and 25 - 27 of Application No. 11/604440 each recite all

the limitations except for the explicit disclosure of a capillary electrophoresis unit.

Swerdlow ('522) teaches a capillary electrophoresis unit (see fig. 1 and column 8,

lines 28 - 45).

It would have been obvious to one of ordinary skill in the art to modify the

apparatus of Application No. 11/604440 to include the capillary electrophoresis unit

taught by Swerdlow ('522) in the biofluid process site because as Swerdlow ('522)

explains combining automated fluidic techniques with capillary electrophoresis obviates

the disadvantages of manual manipulation by technicians and improves efficiency

(column 6, lines 46 – 65).

This is a <u>provisional</u> obviousness-type double patenting rejection.

Response to Arguments

Art Unit: 1753

12. Applicant's arguments with respect to claims 1 – 5 and 7 – 45 have been considered but are most because no claim is rejected under section 102 or 103.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

Art Unit: 1753

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SV/ May 22, 2007

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